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US Pat. Appln. No. 10/539,874

STATUS OF CLAIMS

Claims 1-14 are pending in the application.

REMARKS

Restriction is required to one of the following allegedly patentably distinct species:

I. Claims 1- 4, 9 and 14, drawn to a method for treating tumor diseases in which TRPM8 is overexpressed, comprising administering a pharmaceutical composition comprising TRPM8-activating substance or mixtures containing a TRPM-8 activating substance;

II. Claims 5-7 and 10-13, drawn to a pharmaceutical composition for the treatment of tumor diseases comprising a TRPM8 activation substance or a substance that is selected from the group listed in claim 5;

III. Claim 8, drawn to a method for the treatment of tumor diseases, in which the patient is administered a TRPM8 inhibiting substance

Pursuant to 35 U.S.C. 121 and 372, the Examiner required election of a single group for prosecution on the merits. Further, the Examiner required Applicants to elect a "tumor disease" if either Group I or III is elected. In addition, she required election of a single disclosed species for prosecution on the merits. Regarding the species election, the Examiner has required Applicants to select one "substance" from the group listed in Claim 3, 5, and 9 and one "additive" for the group listed in Claim 4.

In response, Applicants respectfully traverse the restriction requirement and the accompanying remarks. However, since Applicants are required to make an election in order to be responsive to the restriction, Applicants hereby elect Group I (claims 1-4, 9, and 14) and the tumor disease, "prostate cancer."

Applicants state that the Examiner has not met her burden of demonstrating that restriction is required. Specifically, Applicants assert that the Examiner's reasoning for the restriction requirement does not meet the proper standard for a restriction requirement. In the Restriction Action, the Examiner states merely that

> Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because...they lack the same or corresponding special technical features for

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> the following reasons: ***The special technical feature is found in the prior art.*** Claim 5 is drawn to a pharmaceutical composition for the treatment of tumor diseases comprising menthol. Bessette et al. (WO/2000/033857 published June 2000) teach pharmaceutical compositions for sterile injection containing plant essential oils, natural or synthetic, or mixtures or derivatives thereof, for the prevention and treatment of soft tissue cancer in animals...The term ***"galenical"*** is defined in the American Heritage Dictionary (Fourth Edition 2000) as a medicinal preparation composed mainly of herbal or vegetable matter. ***Therefore the substances disclosed in the WO document, all being derived from a plant (herb) would meet this limitation.*** Therefore, in view of Bessette et al. the technical feature recited in claim 5 is ***not novel.*** (emphasis added)

Applicants state that the above remarks do not constitute a sufficient showing to support the proposed restriction. The Examiner cites PCT Rule 13.2 but does not follow its requirements for making a finding of a lack of unity of invention. Applicants state that the subject matter of Groups I-III constitute a single general inventive concept involving the use of substances which activate or inhibit TRPM8. The Examiner has simply not shown otherwise. Rather, the Examiner's reasoning is based on an incorrect premise. That is, the Examiner states that the term "galenical," which appears in composition claim 5, encompasses medicinal preparations composed mainly of herbal or vegetable matter, and thus, the cited Bessette et al. reference meets this limitation, rendering the technical feature recited in claim 5 as not novel. Even assuming that Bessette et al. anticipates claim 5, which it does not, Applicants state that this does not take away from the fact that a single inventive concept ties all of the claims together, i.e., modulating TRPM8 activation and/or inhibition.

Regarding the Examiner's citation of the American Heritage Dictionary for the definition of "galenically," Applicants request further clarification for how the Examiner's observation impacts the unity of invention of the claims. One of ordinary skill in the art would readily recognize that when a substance or additive is "galenically prepared," it refers to a well-known term in the pharmaceutical industry and is used specifically in the discipline of compounding and formulating pharmaceutical compounds that refers to the addition of various auxiliary compounds appropriate to a specific path of administration to create dosage forms suitable for a specific mode of administration such as, for example, intravenous, intraperitoneal or intramuscular injection or infusion. Claim 5 provides for "a pharmaceutical composition...comprising a TRPM8 activating substance...and one or more additives prepared

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galenically for intravenous, intraperitoneal or intramuscular injection or infusion." The fact that the composition constitutes galenically prepared elements does not change the single inventive concept of the claims, that is, the concept of modulating TRPM8 activation and/or inhibition.

Further, under U.S. practice, the Examiner must meet two criteria for a proper requirement for restriction between patentably distinct inventions:

1) the inventions must be independent (see MPEP §802.01, 806.04, 808.01) ***and*** distinct as claimed (see MPEP §806.05 to 806.05(i)); and
2) there must be a ***serious burden*** on the Examiner if restriction is not required (see MPEP 803.02, 806.04(a) to 806.04(i), 808.01(a), and 808.02).

At the very least, Applicants state the Examiner has not satisfied the second criterion. It would not present a serious burden on the Examiner to examine the subject matter of Group I-III and the Examiner as provided no evidence to support that such would require a separate classification, separate status in the art, nor a divergent field of search, as required under MPEP 808.02.

Regarding the species election requirement, the Examiner requests that Applicant elect one "substance" from the group listed in Claim 3, 5, and 9, and one "additive" from the group listed in Claim 4.

In response, Applicants respectfully traverse this rejection. The compounds share a common utility (i.e., they are active with respect to TRPM8). In addition, Applicants state that the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden. As such, even if it is determined that they are directed to independent and distinct inventions, the Examiner must examine all the members of the Markush group in the claim on the merits. (*See In re Harnisch,* 206 U.S.P.Q. 300; *Ex parte Holt and Randell*, 214 U.S.P.Q. 381; *In re Haas*, 198 U.S.P.Q. 334 (Haas II); *In re Weber, Soder, and Boksay,* 198 U.S.P.Q. 328; *Ex parte Brouard Leroy, and Stiot,* 201 U.S.P.Q. 538; *In re Jones*, 74 U.S.P.Q. 149; and *Ex parte Dahlen and Zwilgmeyer,* 42 U.S.P.Q. 208). Regarding the requirement to select an "additive," Applicants state that the additives are trivial and prior art components of the claimed pharmaceutical composition that would not require a separate search and examination.

In light of the foregoing, Applicants request that the Examiner reconsider and withdraw the restriction requirement.

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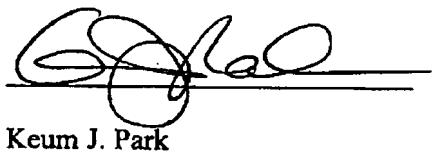
Should the Examiner be of the view that an interview would expedite consideration of the application, request is made that the Examiner telephone the Applicants' attorney at (908) 518-7700 in order that any outstanding issues be resolved.

Respectfully submitted,



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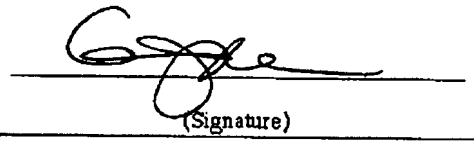

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